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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/695,919	10/26/2000	Martin Gerl	02481.1704	4319

5487 7590 02/09/2005

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EXAMINER

CHEU, CHANGHWA J

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 02/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/695,919	<b>Applicant(s)</b> GERL ET AL.	
	<b>Examiner</b> Jacob Cheu	<b>Art Unit</b> 1641	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 23 November 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☒ Claim(s) 1-15 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |  |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                        |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____   |

### DETAILED ACTION

Applicant's amendment filed on 11/23/2004 has been received and entered into record and considered.

The following information provided in the amendment affects the instant application:

1. Claim 15 is added to the instant application.
2. Currently, claims 1-15 are under examination.

#### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 1, it is not a complete process because there is no standard of C-peptide insulin is measured. Applicant shows the Assay Protocol in page 13, line 25-30, i.e. "1. Standards are prepared in triplicates using 200 ul of each standard concentration." It is thus a necessary step in determining the impurities of insulin, i.e. C-peptide, in a sample by incorporating using the standards.

With respect to claim 1, step (a), "adding a tracer" is vague and indefinite. It is not clear what kind of tracer it is. It is suggested that applicant specify the nature of the tracer for clarification. For instance, a C-peptide tracer.

With respect to claim 1, step (a), it is not clear whether this "tracer" is labeled. It is confusing in this matter since applicant demonstrates labeling procedures in the working

example as to the “*Tracer preparation*” (See page 12, line 20-30)(emphasis added). For instance, applicant uses 120  $\mu$ l of *labeled* Ki256 (10 mg in 1 ml acetonitrile) to label C-peptide tracer. Furthermore, applicant also states “[t]he covalent reaction of the *label* with functional groups in the C-peptide was stopped by addition of 100  $\mu$ l of l-lysine” (See page 12, line 28-30). In addition, claim 8 also recites that the tracer is chemiluminescent. If this is the case, what exactly one should measure, e.g. the tracer or the second antibody having the label?

With respect to claim 1, step (c), “adding a C-peptide second antibody bead” is vague and indefinite. It is not clear what is this “C-peptide second antibody bead.” What nature or function is this “C-peptide second antibody bead.” It is suggested that applicant specifies this second antibody bead, e.g. capturing goat antiinsulin C-peptide antibody (See page 5, line 4-8).

With respect to claim 1, step (c), it is not clear whether this “C-peptide second antibody bead” having label to the sample, or to the first antibody instead. As mentioned beforehand, in page 5, line 4-8, applicant states that the “[p]olystyrol bead coated with secondary antibodies” is for capturing the first antibody, e.g. goat antiinsulin C-peptide antibodies. Therefore, the C-peptide second antibody bead is not specific for the sample but for the first antiinsulin antibodies.

With respect to claim 1, step (d), it is not complete because it is unclear how to “determine the presence of the C-peptide-containing impurities in the sample”, such as either by comparing with a standard curve or measuring the diminishing of the fluorescence.

With respect to claim 15, it shares the same problem as listed in claim 1.

### ***Response to Applicant's Arguments***

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3. Enablement rejections of claims 1-2, 4, 6-14 under 35 U.S.C. 112, first paragraph, are withdrawn based on the newly amended claims.

4. Claims 1-4, 6-9, 11-14 rejected under 35 U.S.C. 103(a) are withdrawn.

***Allowable Subject Matter***

5. Claims 1-15 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

6. The following is an examiner's statement of reasons for allowance: no prior art teaches or suggests using a non-radiolabel assay to detect the C-peptide in a test sample as the recited claims. No prior art teaches or suggests using a tracer and a first antibody specific for C-peptide and a second C-peptide bead having label to detect the C-peptide in recombinant human insulin in a *pH of about 8.5 to about 9.0*. Most of the prior arts function in a physiological pH level, e.g. about 7.2, to detect the C-peptide. The closest prior art is the teachings of Iizuka et al. (Biomedical Res. (1990) Vol. 11, page 417-423) where Iizuka et al. teach using a tracer and two antibodies to measure the C-peptide. However, Iizuka et al. teach using radiolabels, and performing the assay at a physiological level, i.e. pH 7.2-7.4 (See page 419, right column, Table 1; page 420, left column).

***Conclusion***

7. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-282-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

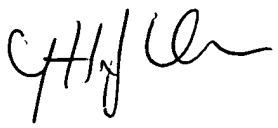
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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

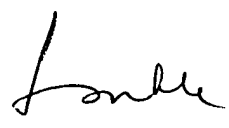
Jacob Cheu

Examiner

Art Unit 1641



January 25, 2005



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02/07/05